MEETING SUMMARY
Region 9 Meeting
March 16, 2011

A UNOS Region 9 meeting was held on March 16, 2011 at the New York Organ Donor Network in New York, NY. Dr. David Conti, Region 9 Councillor, convened the business meeting and welcomed those in attendance. There were 64 individuals in attendance representing 79 percent of UNOS institutional voting members. Those members present unanimously approved the October 2010 regional meeting summary. Dr. Conti provided an update on OPTN/UNOS committee appointments and announced that new regional representatives should receive appointment letters by the end of May. A fall regional meeting date of October 12th was presented. An email will be sent to the region to confirm that this date is convenient for the majority of members.

OPTN/UNOS Update

Brian Shepard, UNOS Director of Policy, provided the OPTN/UNOS Update which included the following information:

- Effective Screening Workgroup
  - Reduce unwanted offers
  - Improve the efficiency of organ placement, in particular for 'marginal' organs offered non-locally
  - Reduce organ wastage and deterioration due to increased CIT
- New Focus on Education
  - Distance-based learning modules
  - A "living" Healthcare Professional Curriculum
  - Roundtable discussions with health care experts
  - Online Forum for member queries
  - Explanation of new policy content
- OPTN/UNOS Policy and Bylaw Re-write
  - Easier to navigate
  - Plain language
  - No substantive changes
- Joint Societies Process
  - Steering Committee with input from UNOS, ASTS, AST, and NATCO
  - First workgroup formed to consider living donor issues, particularly medical evaluation and informed consent.
- Kidney Variance
  - Review of all existing kidney variances
    - Incorporate idea into national kidney system
    - Create a permanent exception for a unique circumstance
    - Design a "final rule" compliant variance
- Chrysalis
  - Multi-year project to update Waitlist Application, Membership Application, and Secure Enterprise
  - Upgrade hardware and software used to run UNet
  - Provided lists of projects to be completed in 2011 and 2012
- Top Five Violations from Site Surveys
  - Patient notification (App B, Sect II F)
  - Notice of waiting time transfer and multiple listing options (3.2.3)
  - ABO verification before implantation (3.1.2)
  - Liver candidate status (3.6.4.1)
  - Candidates' ABO double typing (3.1.4.2)
- Top Five Violations identified outside of Site Surveys
  - Info, packaging & labeling (5.0)
  - Evaluation of potential donors (2.2)
  - Hep+ vascular conduit use w/out explanation (5.10.1)
  - Data submission, timeframes (7.0)
  - Organ allocated or tx'd into recipient not on match run (3.2.4)

- OPTN/UNOS Data: National and Regional Trends
    - Waitlist additions and registrations
    - Deceased and Living Donors

National Committee Reports

Those regional representatives in attendance presented synopses of national committee deliberations. The participants actively discussed many of the issues raised during these reports. Thirteen proposals recently circulated for public comment were considered and the following recommendations agreed upon:

Living Donor Paul Gaglio, MD

Proposal to Improve the Reporting of Living Donor Status

The OPTN currently relies on Living Donor Follow-up (LDF) forms to collect data on the short-term health status of living donors. The transplant community must collectively improve patient information on the LDF form to allow for meaningful analyses to objectively study the short-term effects of living donation. Data on living donors who donated in 2006 through 2008 demonstrate that many programs do not report the status of their living donors at required reporting intervals. **Under this proposal, transplant programs would be required to accurately report if the living donor is alive or dead at the required post operative reporting periods (6, 12 and 24 months).** Follow-up information on donors is especially important in the current climate where the public and the media seek data on the safety of living donation. Without accurate and comprehensive living donor follow-up data, it will not be possible to answer questions and address concerns.

- **Region 9 Vote: 11 yes, 6 no, 4 abstentions**
- **Region 9 Comments: The region discussed this proposal at length. Several members commented that this proposal does not go far enough, that UNOS should require additional information to be completed when submitting living donor follow-up forms. While other members would like UNOS to reconcile each center's living donors with the Social Security Death Master File and provide this information to the transplant centers on a routine basis. The centers would then be responsible for completing each follow-up form. This would save the transplant centers time and money.**

Proposal to Improve the Packaging, Labeling and Shipping of Living Donor Organs, Vessels and Tissue Typing Materials

The majority of living donor organs recovered for transplant are not shipped or transported outside the recovery center, and therefore would not be affected by this proposal. However, the packaging and shipping of living donor organs is increasing, especially as "kidney paired" donation increases throughout the country.

Changes to the policies for the packaging and shipping of deceased donor organs, vessels, and tissue typing materials were approved by the OPTN/UNOS Board in November 2010, and took effect in January 2011. The implementation of these new policies has created a situation where the rules for packaging, labeling and shipping deceased donor organs are more stringent than policies for the packaging, labeling and shipping of living donor organs. In response, this proposal would update living donor policy to more closely align with recent changes to the policy requirements for the packaging, labeling and shipment of deceased donor organs, vessels and tissue typing materials.

The proposal also clarifies procedures when the living donor organ is not packaged, shipped or transported. The Committee anticipates both transplant centers and Organ Procurement Organizations (OPOs) would benefit from the standardization of packaging and shipping requirements for all organs. The Committee further expects that applying the existing requirements for the packaging and shipping of deceased donor organs to living donor organs, vessels and tissue typing materials will increase the safety of living donor organs that are packaged and transported outside the recovery facility.

The proposal would not preclude transplant centers from entering into an agreement with an OPO to coordinate the packaging and shipping of living donor organs, vessels and tissue typing materials.

- **Region 9 Vote: 21 yes, 0 no, 0 abstentions**

Operations and Safety Charlene Hubbell, MT (ASCP), SBB

Proposal to Require Confirmatory Subtyping of Non-A_1 and Non-A_1B Donors
This proposal would require confirmatory subtype testing of blood group A and AB deceased or living donors when subtyping is used for the placement of organs, and the donor is identified to be subtype non-A_1 (e.g A_2) or non-A_1B (e.g A_2B). Blood samples for the initial and confirmatory subtype testing will be required to be taken on two separate occasions and be pre-transfusion specimens only.

- **Region 9 Vote: 18 yes, 0 no, 0 abstentions**

Histocompatibility Committee Update Charlene Hubbell, MT (ASCP), SBB

Organ Procurement Organization Helen Christensen, RN, BSN

Proposal to Standardize Label Requirements for Vessel Storage and Vessel Transport
This proposed change makes the labeling requirements for vessel storage consistent with those for vessel transport. Recent Policy 5.0 changes eliminated the requirement that a label be placed directly on the vessel container for transport and require that the vessel label distributed by the OPTN contractor be attached to the outer barrier of the triple sterile barrier. Policy 5.10.2, currently requires the labeling of the vessel container when vessels are stored and requires the OPO to complete the labeling in the donor OR. As such, there is an inconsistency in vessel labeling requirements. This proposed policy modification will not affect the labeling requirements for vessel transport, and will clarify that containers for vessel storage do not require the vessel container itself to be labeled. The vessels must be placed in a triple sterile barrier, one of which is the rigid container, and labeled with the OPTN distributed label.

- **Region 9 Vote: 20 yes, 0 no, 0 abstentions**

Proposal to Update and Clarify Language in the DCD Model Elements (Organ Procurement Organization and Organ Availability Committees)
The proposed changes to the Donation after Cardiac Death (DCD) Model Elements will clarify and update language for the donation and transplantation community. These Model Elements identify specific requirements that OPOs and transplant centers must include in their DCD policies. As such, the name Model Elements has been changed to "Requirements." DCD is redefined as Donation after Circulatory Death (DCD) in order to accurately reflect the definition of death determined by cardio-pulmonary criteria. The committees also added the following language that mirrors the Centers for Medicare & Medicaid Services (CMS) requirements:

1) OPOs and transplant centers must establish protocols that define the roles and responsibilities of the OPO and the transplant center for all activities associated with the DCD donor and
2) OPOs must have a written agreement with Medicare and Medicaid participating hospitals and critical access hospitals in its service area that describes the responsibilities of both the OPO and hospital concerning DCD.

Additionally, other policies that have the terms "Donation after Cardiac Death" will have to be modified for consistency.

- **Region 9 Vote: 20 yes, 0 no, 0 abstentions**
- **Region 9 Comments: The region approved the proposal but recommends that the following sentence be modified to include the word "recovery": "No member of the Transplant Center surgical recovery team may be present for the withdrawal of life-sustaining medical treatment or ventilated support.**

Pediatric Transplantation Kishore Iyer, MD

Proposal to List All Non-Metastatic Hepatoblastoma Pediatric Liver Candidates as Status 1B
The Pediatric and Liver & Intestinal Organ Transplantation Committees propose that non-metastatic hepatoblastoma pediatric liver candidates should be listed immediately as Status 1B with elimination of the requirement to be listed at a MELD/PELD 30 for 30 days.

Hepatoblastoma is the most common primary liver malignancy in children. Optimal management of these patients usually includes a combination of chemotherapy and complete tumor resection. In some cases, a non-metastatic tumor may not be resectable by conventional means and may require a liver transplant to achieve a complete resection. In order to allow children with non-metastatic hepatoblastoma to be transplanted in a timely fashion, current UNOS policy allows these children to be assigned a MELD/PELD score of 30 at the time of listing. If the candidate is not transplanted within 30 days, the candidate may then be listed as Status 1B. The current Children's Oncology Group protocol for treatment of hepatoblastoma calls for no more than four of six rounds of chemotherapy prior to transplant, reserving two rounds for use following transplant. Since these patients must undergo chemotherapy while awaiting transplant, the optimal window for transplant is very small.

- **Region 9 Vote: 20 yes, 0 no, 1 abstention**

Proposal to Eliminate the Requirement that Pediatric Liver Candidates Must be Located in a Hospital's Intensive Care Unit to Qualify as Status 1A or 1B
The purpose of this proposal is to improve consistency in listing Status IA and IB pediatric liver candidates. The current requirement that a patient be located in the ICU uses location as a surrogate for severity of illness. Since the criteria for admission to an ICU varies from institution to institution across the country, the use of this surrogate creates inequality in Status 1A and 1B listings. In reviewing the other criteria for listing a Status 1A or 1B pediatric candidate, the Pediatric Transplantation Committee believes that these criteria are a stringent enough indicator of severity of disease that the ICU requirement may be eliminated without giving undue advantage to this subset of patients.

- **Region 9 Vote: 20 yes, 0 no, 1 abstention**

Disease Transmission Advisory Carrie Comellas, RN, CPTC, CCTC

Kidney Transplantation Lloyd Ratner, MD

Minority Affairs Lani Jones, PhD, MSW

Organ Availability James Guarrera, MD

Transplant Coordinators Rose Rodriguez, RN, MS, CPNP, CCTC

Public comment proposals continued:

Liver and Intestine Transplantation Lewis Teperman, MD

Proposal for Improved Imaging Criteria for HCC Exceptions
Patients awaiting a liver transplant who are diagnosed with hepatocellular carcinoma (HCC) are eligible for additional priority through MELD/PELD exceptions. Under this proposal, HCC lesions would be classified more precisely according to newly-defined imaging criteria, with only Class 5 potentially eligible for automatic upgrades.

Currently, HCC exceptions are based on diagnostic criteria that rely on imaging characteristics rather than liver

biopsy. The attendees of a multi-disciplinary HCC Consensus Conference held November 2008 made specific recommendations regarding the appropriate imaging criteria to properly determine HCC staging. The Committee is proposing to incorporate these recommendations into Policy 3.6.4.4. A survey of all U.S. liver transplant programs in October 2010 indicated strong support for these changes.

- **Region 9 Vote: 19 yes, 0 no, 2 abstentions**

Proposal to Reduce Waiting List Deaths for Adult Liver-Intestine Candidates
The proposal is intended to reduce the death rate on the waiting list for adult combined liver-intestine candidates by providing broader access to donor organs. Waiting list death rates in adult candidates awaiting a combined liver-intestine transplant are nearly three times higher than those waiting for a liver alone. This is a numerically small patient population with high waiting list mortality rates due to the need for two organs and donor organ size constraints.

- **Region 9 Vote: 0 yes, 13 no, 8 abstentions**
- **Region 9 Comments: The region did not approve this proposal and provided the following comments: 1) This proposal will disadvantage small statured females and other candidates awaiting a liver alone in Region 9. 2) The region commented that the committee seems to be selecting when and how they want broader sharing, but not pursuing broader sharing on a regional or national level. 3) The proposal is written from a national perspective, but the region wants to ensure that the NY statewide liver sharing agreement remains and that the third category of the algorithm should read: "NY statewide candidates with MELD/PELD scores >=29 in descending order of mortality risk scores".**

Proposed Committee-Sponsored Alternative Allocation System (CAS) for Split Liver Allocation
This committee-sponsored AAS (CAS) is intended to increase the number of transplants and reduce waiting list deaths by transplanting the right lobe into an adult patient and the remaining lobe/segment into a second candidate. The CAS will potentially reduce waiting times for liver candidates overall, because the liver pool would be expanded by splitting livers that otherwise would not be split. In November 2010, the Board of Directors approved two alternative allocation systems (AAS) to Policy 3.6.11 (Allocation of Livers for Segmental Transplantation). At that time, the Board asked that the Liver Committee consider developing a committee-sponsored AAS (CAS) that would allow other Regions and OPOs to participate in a split liver AAS. This proposed CAS is based on the approved Region 2 and OneLegacy AASs, but will provide one standard model for all participants to follow. In summary, if an adult candidate is offered a liver through the standard policy or an approved-AAS (i.e., via the match run) who has been determined to be suitable for a segmental liver transplant (known as the index patient), the candidate's transplant center may transplant the right lobe into the index patient. The center may then transplant the left lobe/segment into any other medically suitable listed patient at that institution or an affiliated pediatric institution (if applicable), in order of the match run.

- **Region 9 Vote: 20 yes, 0 no, 0 abstentions**
- **Proposal approved as written**

Thoracic Organ Transplantation Alan Gass, MD

Proposal to Encourage Organ Procurement Organizations (OPO) to Provide Computed Tomography (CT) Scan if Requested by Transplant Programs, And to Modify Language in 3.7.12.3 for Currency and Readability
The Thoracic Committee proposes the addition of CT scan to Policy 3.7.12.4 (Desirable Information for Lung Offers). An OPO is encouraged to provide this information if it is requested to do so by a transplant program. The proposed policy does not require a transplant program to request a CT scan.

Deceased donor lung or lungs may have contusions or infiltrates or malignant nodules, which may not be visible in a chest x-radiation (CXR). A computed tomography (CT) scan can identify these contusions, preventing the transplant of a damaged lung. The CT scan can also identify nodules which may be malignant, preventing the transmission of cancer or tumors to the recipient.

- **Region 9 Vote: 14 yes, 0 no, 0 abstentions**
- **Region 9 Comments: One member commented that not all OPO's SAC fees include CT scans and centers may be billed separately for the scan.**

Proposal to Require Updates of Certain Clinical Factors Every 14 Days for Lung Transplant Candidates with Lung Allocation Scores (LAS) of at Least Fifty, And to Modify Policy 3.7.6.3 for Currency and Readability

The Thoracic Committee proposes that Policy 3.7.6.3.2 require transplant programs to update in no less than 14 days, any observed changes in clinical values most important to determining a candidate's Lung Allocation Score for candidates whose scores are 50 or higher. The proposal would require transplant programs to update candidate data for high-LAS candidates whenever changes occur to assisted ventilation, supplemental oxygen, or current PCO_2.

Policy 3.7.6.3.2 requires a transplant program to update its candidates' clinical data in UNet^{SM} values every six months. A candidate whose lung allocation score is 50 or higher is likely receiving therapeutic interventions that may decrease her or his score, but does not currently require more frequent updates if the candidate's health improves.

- **Region 9 Vote: 12 yes, 0 no, 0 abstentions**

Proposal to Allow Outpatient Adult Heart Transplant Candidates Implanted with Total Artificial Hearts (TAH) Thirty Days of Status 1A Time

This interim policy is in effect, and will expire on December 1, 2011 without further action by the Board of Directors. The Thoracic Committee will consider public comment and make a recommendation to the Board of Directors before the expiration date.

On November 9, 2010, the OPTN/UNOS Board of Directors approved an interim policy, concurrent with public comment, for adult heart transplant candidates implanted with a TAH and discharged from the hospital. These candidates may now be listed as Status 1A for 30 days. When this 30-day time period ends, if these candidates do not qualify for Status 1A by other existing criteria, they must be downgraded; and, they may be Status 1B.

Recent availability of a portable driver has allowed some candidates with TAHs to await heart transplantation as outpatients. Prior to the availability of this new instrument, all candidates with TAHs remained inpatients. Policy allows all inpatient TAH candidates to be classified as Status 1A for 14 day periods; however, policy previously prevented outpatient candidates implanted with TAHs to be listed as Status 1A unless they qualified by other criteria. There are no data to suggest that the medical urgency of an inpatient candidate with a TAH implant is different from an outpatient candidate with a TAH implant.

- **Region 9 Vote: 12 yes, 0 no, 0 abstentions**

With no further business, the meeting was adjourned.